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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,342	03/17/2004	Peter M.J. Bedding	7593-CIP	3643

22922 7590 04/19/2010

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
04/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPAdmin@reinhartlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/802,342	BEDDING ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,19-22 and 24-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17, 19--22 and 24-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/14/2009; 01/15/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 01/14/2010, IDS filed 10/14/2009, and IDS filed 01/15/2010.

Claims 1-22, 24-38 are previously prosecuted.

Claim 18 is currently canceled.

Claims 1-17, 19-22 and 24-38 are pending and included in the prosecution.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 4, 10-17, 19-22, 24-28, 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs (US 2002/004988, currently listed on PTOL 892) combined with Hallfrisch et al. ("Diets containing soluble oat extracts improve glucose and insulin responses of moderately hypercholesterolemic men and women", currently listed on PTO 892 and copy is provided) and the article Alltech (of record).

Applicant Claims

Applicants' present claim 1 is directed to a nutritional product comprising: a polar lipid supplement that has been isolated from its natural source which polar lipid supplement is high in galactolipids and antioxidants; a soluble fiber source that has

been fractionated from its natural origin which soluble fiber source exerts a beneficial effect on health; a nutricine which enhances growth and/or strengthens the immune system consisting of a source of dietary nucleotides; and a protein concentrate supplement.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Fuchs teaches composition for administration to human and companion animals comprising protein source, lipid source, carbohydrate source and micronutrients comprising at least vitamin E and vitamin C (abstract; ¶ 0030). The composition is useful to treat conditions such as ulcerative colitis (¶ 0064). The composition comprising whey protein concentrate and sources of amino acids comprising threonine and teaches that the nutritional composition used as indirect source to promote endogenous glutamine production (¶ 0041-0043, 0063-0064). The amino acids provides between 15-18% of total energy of the composition (¶ 0021). The lipid source forms 18-40% of the composition and comprises high oleic acid sunflower and safflower, soy oil, olive oil, and fractionated coconut oil (¶ 0044, 0048). The composition comprises source of soluble fibers and oligosaccharides that affect the host by selectively stimulating growth and activity of bacteria in the colon which have the potential to improve host health (¶ 0051). The composition comprises prebiotic fibers to prevent or decrease the growth of pathogens (¶ 0052). The composition is rich in vitamins E, and comprises other vitamins such as vitamin B_{12} and minerals (¶ 0050). The composition comprises guar gum and

emulsifiers (¶ 0051, 0057). The composition further comprises medicines (¶ 0064). The composition is nutritional supplement in the form of powder, liquid concentrate, bar/snack or ready to use formulation (¶ 0036). Fuchs teaches that the amount and regimen of administration of nutritional supplement given to patient vary depending on patient's condition, body weight, age, and other sources of nutrition, and may be given from 2 to 5 times a day or in single daily dose (¶ 0066).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Fuchs teaches soluble fibers, however, does not explicitly teach soluble fibers that have been fractionated from original source such as oat and its amount as claimed by claims 1 and 10-17. Although the reference teaches proteins and amino acids that contain nucleotides, however, the reference does not explicitly teach nucleotide from yeast cell as claimed by claims 1 and 19-22 and additional nutricine materials from yeast cell wall as claimed by 24-26. Fuchs teaches mineral, however, does not explicitly teach organic selenium as claimed by claims 35-37.

Hallfrisch teaches that diet containing soluble oat extracts improve glucose and insulin responses of moderately hypercholesterolemic subjects. The high amount of soluble β-glucan in oat is responsible for beneficial effects on glucose tolerance and blood lipid. The study done by the reference used 1% or 10% soluble β-glucan. The reference teaches that to concentrate soluble β-glucan from oat is known patented method and soluble β-glucan can be incorporated as fibers into varieties of food to

significantly affect risk factors for diseases without altering palatability or acceptability of the diet (page 379, abstract, introduction; page 381, results; page 382, discussion).

Alltech teaches enhancement of animal physiological condition through nutrition including Yea-Sacc®1026 as yeast culture as a performance enhancing for animals. Yea-Sate1026 is an active yeast culture comprised of viable cells from the strain Saccharomyces cerevisiae 1026. Yea-Sacc1026 is the only yeast culture that can be called rumen modifier. Alltech disclosed Bio-Mos that is a phosphorylated mannanoligosaccharide derived from the cell wall of the yeast and has been scientifically proven around the world to be beneficial to animals. Bio-Mos has shown positive results alone and in combination with antibiotic programs in animal diets. Alltech teaches that organic selenium is crucial mineral as protective in a number of metabolic diseases and essential for the basic functions of growth and reproduction and improves animal performance.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a nutritional supplement comprising amino acids source, protein concentrate, lipid source and soluble fibers as taught by Fuchs, and further add or replace the soluble fibers with 1-10% soluble oat β-glucan soluble fibers taught by Hallfrisch. One would have been motivated to do so because Hallfrisch teaches that soluble β-glucan fibers from oat can be incorporated in diet to significantly affect risk

factors for diseases without altering palatability or acceptability of the diet. One would reasonably expect formulating palatable acceptable nutritional supplement comprising amino acids, protein concentrate, lipid source and soluble oat β-glucan fibers to affect the risk for diseases.

Additionally, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide nutritional supplement comprising amino acids, protein concentrate, lipid source and soluble oat β-glucan fibers as taught by the combination of Fuchs and Hallfrisch, and further add cultured yeast cells or replace amino acids with cultured yeast cells and add BIOMOS as taught by Alltech. One would have been motivated to do so because Alltech teaches that cultured yeast cells enhances of animal physiological condition and performance and BIOMOS is scientifically proven around the world to be beneficial to animals. One would reasonably expected formulating nutritional supplement comprising cultured yeast cells, protein concentrate, lipid source and soluble oat β-glucan fibers that is beneficial to subject and enhances subject physiological condition and performance.

Furthermore, one having ordinary skill in the art would have been motivated to provide nutritional supplement comprising amino acids, protein concentrate, lipid source, soluble oat β-glucan fibers and minerals as taught by the combination of Fuchs and Hallfrisch, and further replace the mineral taught by Fuchs with organic selenium taught by Alltech. One would have been motivated to do so because Alltech teaches that organic selenium is crucial mineral as it is protective in a number of metabolic diseases and essential for the basic functions of growth and reproduction and improves

animal performance. One would reasonably expected formulating animal feed comprises amino acids, protein concentrate, lipid source, soluble oat β-glucan fibers and organic selenium that provides advantage to gastrointestinal tract and protect animal against metabolic diseases.

The available Alltech information, does not provide the amount of cultured yeast cells, Bio-Mos or organic selenium. However, those of ordinary skill in the art would have been readily optimized effective dosages as determined by good medical practice and the clinical condition of the individual subject because Fuchs teaches that the amount and regimen of administration of nutritional supplement given to patient vary depending on patient's condition, body weight, age, and other sources of nutrition, and may be given from 2 to 5 times a day or in single daily dose. Determination of the appropriate dosage for treatment involving each of the above mentioned ingredients would have been routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation. One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

5. Claims 2, 3 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs combined with Hallfrisch and Alltech as applied to claims 1, 4, 10-17, 19-22, 24-28, 33-38 above, and further in view of Brooke Boocock et al. (US 4,053,492, currently listed on PTO 892).

Applicant Claims

Applicants' present claims 2, 3 and 5-9 recite the lipid component of the nutritional composition of claim 1 as being derived from oat.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The combination of Fuchs, Hallfrisch and Alltech teaches nutritional supplement comprising threonine cultured yeast cells, protein concentrate, vitamins and minerals, BIOMOS, fractioned lipid source and soluble oat β-glucan.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although Fuchs teaches nutritional supplement comprising lipid source and teaches fractionated lipid source, however, the reference does not explicitly teach lipid from oat and its amount as claimed by claims 2, 3 and 5-9.

Boocock teaches oil extracted from oat that is useful for food industry and contains natural antioxidant that prevents rancidity of the oil (abstract; col.1, lines 7-22).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a nutritional supplement comprising cultured yeast cells, protein concentrate, vitamins and minerals, BIOMOS, lipid source and β-glucan soluble fibers as taught by the combination of Fuchs, Hallfrisch and Alltech, and replace the lipid source with lipid/oil from oat that is taught by Boocock. One would have been motivated to do so because Boocok teaches that oat oil is rich in antioxidants that prevent rancidity of the oil. One would reasonably expect formulating nutritional supplement comprising cultured yeast cells, protein concentrate, lipid source extracted from oat and comprises antioxidant and soluble oat β-glucan fibers wherein rancidity of the composition is prevented.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Those of ordinary skill in the art would have been readily optimized effective amount of oat lipids as determined by good medical practice and the clinical condition of the individual subject because Fuchs teaches that the amount and regimen of

administration of nutritional supplement given to patient vary depending on patient's condition, body weight, age, and other sources of nutrition, and may be given from 2 to 5 times a day or in single daily dose. Determination of the appropriate dosage for treatment involving each of the above mentioned ingredients would have been routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation. One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

6. Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs combined with Hallfrisch and Alltech as applied to claims 1, 4, 10-17, 19-22, 24-28, 33-38 above, and further in view of Bengmark et al. ("Gastrointestinal surface protection and mucosa reconditioning", currently provided).

Applicant Claims

Applicants' present claims 29-32 further recite that the amino acid is glutamine.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The combination of Fuchs, Hallfrisch and Alltech teaches nutritional supplement comprising threonine cultured yeast cells, protein concentrate, vitamins and minerals,

BIOMOS, fractioned lipid source and soluble oat β-glucan. Fuchs further shows interest in stimulating endogenous glutamine production.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Fuchs further shows interest in stimulating endogenous glutamine production, Fuchs however does not teach the nutritional supplement comprises glutamine as claimed by claims 29-32.

Bengmark teaches that amino acids and particularly glutamine used for reconditioning the intestinal mucosa (see provided abstract).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a nutritional supplement comprising cultured yeast cells, protein concentrate, vitamins and minerals, BIOMOS, lipid source and β-glucan soluble fibers as taught by the combination of Fuchs, Hallfrisch and Alltech, and further add glutamine taught by Bengmark to the supplement. One would have been motivated to do so because Fuchs is interested in stimulating endogenous glutamine production, and because Bengmark teaches that glutamine used for reconditioning the intestinal mucosa. One would reasonably expect formulating nutritional supplement comprising cultured yeast cells, protein concentrate, lipid source, and soluble oat β-glucan fibers

wherein the composition has improved reconditioning effect on the gastro-intestinal mucosa.

Regarding the amounts of glutamine, one having ordinary skill in the art would have been determined the amounts glutamine in the composition according to individual user and condition to be treated because Fuchs teaches that the amount and regimen of administration of nutritional supplement given to patient vary depending on patient's condition, body weight, age, and other sources of nutrition, and may be given from 2 to 5 times a day or in single daily dose.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

7. Applicant's arguments with respect to claims 1-8, 1-23 and 38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611